

1K964944

FEB 10 1997

Original 510(k)  
Round Dental Bur

Section 6

**letterhead**

**510(k) Summary**

**Manufacturer Information:**

Submitter's Name: Steri-Oss Inc.  
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Yorba Linda, CA 92887  
U.S.A.  
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Steri-Oss Inc.  
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Date Prepared: December 1996

**Device Name:**

Common Name: Dental Bur  
Trade Name: Round Dental Bur  
Standard Product Nomenclature  
(Classification Name): Bur, Dental

**Predicate Device:**

Substantial equivalence is claimed to Brasseler Corporation's Round Dental Burs.

**Device Description:**

**How The Device Functions:**

Dental burs are rotary cutting devices. Dental burs are shaped to provide a cutting action when simultaneously rotating and advanced forward into the target material with the application of pressure.

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**Device Description (continued):**

**Scientific Concepts:**

A rotary cutting device.

**Characteristics:**

Round Dental Burs are manufactured from carbide steel or tungsten carbide and may have friction grip or right angle latch shanks..

**Intended Use:**

The intended use is to cut hard structures in the mouth, such as teeth or bone.

One such application is to cut holes in cortical plate bone preparatory to creation of an osteotomy for placement of dental implants.

**Comparison to Predicate:**

The following table provides a comparison of the technological characteristics of Steri-Oss' Round Dental Burs to the predicate burs.

**Product Comparison**

Specification/ Characteristic	Predicate: Brasseler Corporation's Round Dental Burs	New Product: Steri-Oss' Round Dental Burs
<b>DESIGN</b>		
Size (overall length)	19 - 22 mm	Same
Diameter (across head)	0.6 - 2.3 mm	Same
Diameter (Shaft)	1.6 - 2.35 mm	Same
<b>MATERIAL</b>		
Body material	Carbide Steel	Same
<b>PACKAGING</b>		
Container	Unknown	Plastic vial and cap with protective layers of foam
Sterility	NOT Provided Sterile	Same

**Performance Data:**

Not applicable.